II. REMARKS

Formal Matters

Claims 2-5, 7, 10, 14, 20, 21, 23-25, and 27-39 are pending after entry of the amendments set forth herein.

Claims 2-5, 7, 10, 14, 20, 21, 23-25, and 27-33 were examined. Claims 27-32 were allowed. Claims 3, 5, 24, and 25 were objected to. Claims 2, 4, 7, 10, 14, 20, 21, 23, and 33 were rejected.

Claims 10 and 23 are amended. The amendments to the claims were made solely in the interest of expediting prosecution, and are not to be construed as an acquiescence to any objection or rejection of any claim. The amendment to claim 23 is merely editorial in nature. Support for the amendments to claim 10 is found in the claims as originally filed, and throughout the specification, in particular at the following exemplary locations: Example 6; and paragraph 0042. Accordingly, no new matter is added by these amendments.

Claims 34-39 are added. Support for new claims 34-39 is found in claims 2-7 as originally filed, and throughout the specification. Accordingly, no new matter is added by these new claims.

Applicants respectfully request reconsideration of the application in view of the remarks made herein.

Allowable subject matter

Applicants note with gratitude that claims 27-32 were deemed allowable.

Claim objections

The Office Action stated that claims 3, 5, 24, and 25 were objected to as depending from a rejected base claim. The Office Action stated that claims 3, 5, 24, and 25 would be allowable if re-written in independent form including all of the limitations of the base claim and any intervening claims.

New claims 34-39 are added, which correspond to claims 3, 5, 24, and 25, re-written in independent form. Accordingly, new claims 34-39 should be allowable.

Rejection under 35 U.S.C.§112, first paragraph

Claims 10, 14, 20, 21, and 33 were rejected under 35 U.S.C.§112, first paragraph, as allegedly lacking enablement.

The Office Action stated that the specification does not reasonably provide enablement for a method for reducing a Th2 immune response to a plant allergen in any subject or without the co-administration of an effective amount of the polynucleotide composition of claim 2 and an effective amount of the ISS in any subject. Applicants respectfully traverse the rejection.

Without conceding as to the correctness of this rejection, claim 10 is amended to recite a method for reducing a Th2 immune response to a plant allergen in a mammalian subject, comprising co-administering to the mammalian subject the recited polynucleotides.

Applicants submit that the rejection of claims 10, 14, 20, 21, and 33 under 35 U.S.C. §112, first paragraph, has been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejection.

Rejection under 35 U.S.C.§102(b)

Claim 2 was rejected under 35 U.S.C.§102(b) as allegedly anticipated by Singh et al. (U.S. Patent No. 5,965,455; "Singh") as evidenced by Schultz et al. ((1987) *Gene* 54:113-123; "Schultz").

The Office Action stated that the teachings of Singh meet all the limitations of the instant claim as evidence by Schultz; and stated that Singh anticipates instant claim 2. Applicants respectfully traverse the rejection.

The Office Action stated that Singh discloses nucleic acid sequences coding for two ryegrass pollen allergen Lol p Ib family members, and fragments that do not contain native signal sequences. Singh discusses cloning of cDNAs encoding the rye grass pollen allergens Lol p Ib.1 and Lol p Ib.2. Singh, Example 1 and Example 9. Singh states that cDNAs encoding Lol p Ib.1 and Lol p Ib.2 include signal sequences. Singh, column 7, lines 28-52.

However, nowhere in Singh is there any disclosure or suggestion of a polynucleotide comprising a nucleic acid encoding a plant allergen modified to include a signal sequence derived from a phylum or

kingdom other than the phylum or kingdom from which the plant allergen is derived. Accordingly, Singh cannot anticipate the instant invention as claimed.

The Office Action stated that Singh specifically teaches that a suitable vector for expression in yeast cells includes the vector taught by Schultz. The Office Action cited the Singh, column 11, lines 18-21. However, at column 11, lines 18-21, Singh states: "[s]uitable vectors for expression in yeast include ... JRY88 (Schultz et al. (1987) *Gene* 54:113-123)." ***JRY88 is not a vector***. JRY88 is a yeast strain. Schultz, page 114, column 2 under "Yeast manipulations."

The Office Action stated that Schultz discusses a yeast expression vector (pYEBVC-1) for expressing a protein that contains a pre-pro-leader polypeptide. However, Singh does not disclose the pYEBVC-1 vector. Singh does not disclose any polynucleotide comprising a nucleic acid encoding a plant allergen, wherein the nucleic acid encoding the plant allergen is operably linked to a signal sequence derived from a second phylum or kingdom. Moreover, Schultz merely discusses production of a viral glycoprotein in yeast cells. Accordingly, Singh cannot anticipate claim 2.

Applicants submit that the rejection of claim 2 under 35 U.S.C. §102(b) has been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejection.

Rejections under 35 U.S.C.§103

Claims 2 and 4 were rejected under 35 U.S.C.§103 as allegedly unpatentable over Singh as evidenced by Schultz and in view of Kim et al. ((1997) *Gene* 199:293-301; "Kim"). Claims 7 and 23 were rejected under 35 U.S.C.§103 as allegedly unpatentable over Rogers et al. (U.S. Patent No. 5,776,761; "Rogers") in view of Singh and Schultz.

Claims 2 and 3 over Singh in view of Kim

The Office Action stated that: 1) Singh discloses nucleic acid sequences coding for two ryegrass pollen allergen Lol p Ib family members, and fragments that do not contain native signal sequences; 2) Singh specifically teaches that a suitable vector for expression in yeast cells includes the vector taught by Schultz; 3) Singh does not specifically teach the preparation of nucleic acid sequences coding for two ryegrass pollen allergen Lol p Ib family members, and their peptide fragments, wherein at least one

codon of the nucleic acid sequences encoding the allergic antigens is modified to an analogous codon of a host species; and 4) Kim teaches that a correlation exists between high expression and the use of selective codons in a given organism. The Office Action stated that it would have been obvious to modify the nucleic acid sequences encoding ryegrass pollen allergen Lol p Ib family members of Singh by substituting codon bases of these nucleic acids with analogous codon bases commonly used in a given selected expression host cell in order to increase expression efficiency. Applicants respectfully traverse the rejection.

As discussed above, Singh neither discloses nor suggests a polynucleotide comprising a nucleic acid encoding a plant allergen modified to include a signal sequence derived from a phylum or kingdom other than the phylum or kingdom from which the plant allergen is derived. Kim does not cure the deficiency of Singh. Kim merely discusses codon optimization for high level of expression of human erythropoietin in mammalian cells. Accordingly, Singh, alone or in combination with Kim, cannot render instant claims 2 and 4 obvious.

Claims 7 and 23 over Rogers in view of Singh and Schultz

The Office Action stated that: 1) Rogers discloses cDNAs encoding Amb aI allergic proteins or peptides from ragweed; 2) Rogers does not specifically teach the preparation of nucleic acid sequences coding for Amb a1 allergic proteins or peptides, wherein such nucleic acids contain a heterologous signal sequence; 3) Singh discloses nucleic acid sequences coding for two ryegrass pollen allergen Lol p Ib family members, and fragments that do not contain native signal sequences; and 4) Singh specifically teaches that a suitable vector for expression in yeast cells includes the vector taught by Schultz. The Office Action stated that it would have been obvious to clone and express the nucleic acid sequences encoding Amb aI allergic proteins or peptides of Rogers in a yeast expression system taught by Singh and Schultz for the preparation of Amb aI allergic proteins or peptides. Applicants respectfully traverse the rejection.

As the Office Action stated, Rogers, the primary reference, does not specifically teach the preparation of nucleic acid sequences coding for Amb a1 allergic proteins or peptides, wherein such nucleic acids contain a heterologous signal sequence. Rogers neither discloses nor suggests a nucleic acid sequence coding for Amb a1 allergic proteins or peptides, wherein the nucleic acid is operably linked to a heterologous signal sequence.

Singh cannot cure the deficiency of Rogers. As discussed above, Singh does not disclose or suggest a polynucleotide comprising a nucleic acid encoding a plant allergen modified to include a signal sequence derived from a phylum or kingdom other than the phylum or kingdom from which the plant allergen is derived. Accordingly, Singh neither discloses nor suggests a polynucleotide composition comprising a nucleic acid encoding an Amb aI allergen modified by deletion of a native Amb a1 signal sequence, wherein the nucleic acid encoding the Amb a1 allergen is modified to comprise a heterologous signal sequence operably linked to the Amb a1 allergen-encoding sequence. Schultz cannot cure the deficiency of Rogers. Schultz merely discusses production in yeast cells of a viral glycoprotein.

In view of the above discussion, Rogers, alone or in combination with Singh and Schultz, cannot render instant claims 7 and 23 obvious.

Conclusion as to the rejections under 35 U.S.C.§103

Applicants submit that the rejection of claims 2, 4, 7, and 23 under 35 U.S.C. §103 has been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejection.

III. CONCLUSION

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number UCAL-203.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

Date: Sept. 11, 2003

By: _____
Paula A. Borden
Registration No. 42,344

BOZICEVIC, FIELD & FRANCIS LLP
200 Middlefield Road, Suite 200
Menlo Park, CA 94025
Telephone: (650) 327-3400
Facsimile: (650) 327-3231

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